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Dated 3 November 1999

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Cardiff Road
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1. Your reference

P22412/LXM/BOU

2. Patent application number
(The Patent Office will fill in this part)

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3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Giltech Limited
12 North Harbour Estate
AYR
KA8 8AA

Patents ADP number *(if you know it)*

4015822001

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom

4. Title of the invention

"Alginate Foam"

5. Name of your agent *(if you have one)*

Murgitroyd & Company

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

373 Scotland Street
GLASGOW
G5 8QA

Patents ADP number *(if you know it)*

1198013

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

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Continuation sheets of this form	
Description	18
Claim(s)	–
Abstract	–
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Priority documents	–
Translations of priority documents	–
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	–
Request for preliminary examination and search *(Patents Form 9/77)*	–
Request for substantive examination *(Patents Form 10/77)*	–
Any other documents *(please specify)*	–

11. I/We request the grant of a patent on the basis of this application.

Signature Murgitroyd & Co Date 6.10.1998

Murgitroyd & Company

12. Name and daytime telephone number of person to contact in the United Kingdom Beverley Ouzman 0141 307 8400

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FOAM

The present invention is concerned with a foamable formulation and the foam formed therefrom.

A wide variety of gels, creams, ointments, lotions and other formulations are available for application to a body surface. The exact content of these compositions will vary depending upon the purpose of application. For example, a formulation may be applied to clean a body surface, to promote healing of any wound or injury, to prevent an exposed wound on the body from drying out, to prevent infection, etc. In certain circumstances the composition may include an active ingredient.

In our International Patent Application published 13 June 1996 under No WO-A-96/17595 we describe a foamable formulation which comprises a foamable carrier or gelling agent, for example an alginate gel, and an active ingredient, such as a water soluble glass powder.

The product described in WO-A-96/17595 represented a considerable advance over the use of gel or cream.

We have now found that by including a precipitant for the gelling agent, in a slow-release form within the composition, further improvements with regard to the setting time of the foam and its stability can be achieved. In particular, the added stability enables a pre-foamed pad to be sterilised by irradiation or other conventional means.

Thus, the present invention provides a formulation comprising a foamed gelling agent admixed with a slow-release precipitant therefor. The gelling agent may be any agent capable of forming a foam, although preferably the gelling agent is physiologically compatible and non-irritant when maintained in contact with the body surface. The gelling agent may be a gel, for example a sodium alginate gel, carageenan gel, sodium carboxymethylcellulose gel or mixtures thereof.

The precipitant is desirably intimately admixed throughout the whole of the foamed gelling agent, preferably during the foaming process. In certain circumstances however the presence of the precipitant on one surface of the foamed gelling agent may be sufficient to cause stabilisation of the foam. Examples of precipitants include stabilising crosslinking agents which render the gelling agent insoluble. Examples include polyvalent metal ions of calcium, zinc, copper, silver or aluminium as well as borates, glyoxal and amino-formaldehyde precondensates.

The role of the precipitant is to stabilise the foamed gel so that a stable foam is produced. Generally, the stable foam should be produced within a reasonable time period since if the precipitant is too slow-acting, the foam structure will have collapsed prior to

stabilisation. However, a very fast acting precipitant may not allow sufficient time for the admixed gel to be foamed. Desirably, the precipitant stabilises the gel over a time period of 1 minute to 120 minutes, preferably within 30 minutes. The solubility of the precipitant and hence the setting time of the foam may be varied by adjusting the pH of the composition especially where the precipitant is based upon a calcium salt. Generally, the solubility of a calcium salt will be increased by lowering the pH. Typical pH adjusters include organic acids such as acetic, adipic, citric, fumeric, lactic and tartaric acids.

Suitable precipitants include calcium citrate, calcium carbonate, calcium phosphate, calcium hydrogen phospate ($CaHPO_4$), barium carbonate, barium phosphate, barium sulphate, barium chloride and zinc carbonate.

Where the gelling agent comprises an alginate gel, a carageenan gel or a carboxymethylcellulose gel one preferred precipitant is a calcium salt. Whilst calcium citrate has been used in the examples, other slowly dissolving calcium salts are also suitable.

Where the gelling agent comprises carboxymethylcellulose gel one preferred precipitant is an aluminium salt.

In one embodiment the gelling agent and precipitant are packaged separately and only admixed during the foaming process or subsequent to foaming.

Optionally, the formulation may comprise other additives such as decompactants which promote the desired foam structure or other foaming agents, plasticisers, humectants, preservatives, additives,

sequestering agents or active ingredients such as antimicrobial agents, growth factors, hormones, living cells, etc.

The foam may be applied directly to the body area and allowed to produce a stable foam protective cover, for example over a wound.

Alternatively, the foam can be produced onto a mould or other surface area, allowed to cure and then applied to the body surface. Optionally, the foam may be applied about a substrate (for example cloth, mesh, non-woven pad of alginate fibres, nylon, rayon, polylactid acid, polyglycolic acid, polycaprolactone or biocompatible glass fibres) which are then integrated into the foam pad produced.

As an example, the foam may be used to treat dermatological conditions (including psoriasis, atopic and allergic eczema). It may be convenient in this embodiment for the foam to deliver an active ingredient normally used to alleviate such conditions, for example a steroid such as hydrocortisone.

In another embodiment the foam may be used to treat burns or scalds, including sunburn.

In another embodiment the foam may be applied cosmetically, and for example may include skin moisturising agents, nutritional agents and growth factors suitable to promote skin regeneration. A foam intended for cosmetic use may include colorants or pigments so that the foam may be applied to the skin as a cosmetic or to disguise any blemishes in the skin.

The foam may be used prophylactically. In particular a

foam containing a UV blocking agent may be applied to exposed areas of the skin to protect it from the effects of the sun.

The formulation of the invention is applied to the body site of interest in the form of a foam and it is therefore essential that the composition undergoes a foaming process before application to the body. In the foaming process gas is forced into or is formed within the formulation to entrap small bubbles of gas therein, thereby forming the foam. Any suitably gas or gas producing system can be used to produce the foam. Mention may be made of butane and nitrous oxide, but other gases like air, nitrogen, hydrofluorocarbons such as HFC134a or 227, hydrocarbons like propane, isopropane or a mixture thereof, are also suitable. Conveniently the foam may be produced by conventional means such as by using aerosol technology.

The formulation according to the present invention may be stored in any convenient container until required. Generally, the container will be designed to preserve the sterile nature of the formulation. Conveniently the container will be provided with means to foam the composition when required. Details are given in WO-A-96/17595.

Generally, the foam will be produced from sterile ingredients.

Prior to the foaming process, the foamable carrier is preferably in the form of a gel. The gel may be sterilised and this is generally desirable where the foam is intended for medical use. Usually, sterilisation will take place by autoclaving the formulation, since this is currently the most economic

means of achieving sterilisation. Autoclaving at temperatures of from 100°C to 125°C for under ½ hour is normally sufficient. Generally, the autoclaving process should be as mild as possible, whilst being sufficient to sterilise the formulation. For example, autoclaving at temperatures of about 121°C for 15-20 minutes is acceptable. The autoclaved formulation may then be foamed when cool. It is also possible, however, to sterilise the formulation by other means, for example by γ-irradiation or e-beam irradiation. It has been found that autoclaving the gel may cause the MW of the foamable carrier to be slightly reduced. Consequently it may be desirable to select a foamable carrier having a higher MW than that ultimately required.

The foam forms an air-tight cover around any wound or injury to which it is applied, and this prevents that area from drying out and may also combat infection. The advantages of applying a topical product in the form of a foam include:

1. Easy rapid application,
2. Conforms to surface irregularities,
3. Insulates the wound,
4. Cools the tissues,
5. Offers antibacterial action to prevent infection,
6. Biocompatibility with tissue,
7. Suitable for use as a vehicle for the administration of pharmaceutical agents, and/or
8. Maintains a moist environment.

Generally, the formulation of the present invention will be applied directly to the body site of interest

in the form of a foam, the foam being produced from any suitabl device (such as an aerosol) immediately before application. It is, however, possible for a quantity of the foamed formulation to be produced and then applied onto the body site by any suitable means, for example by hand or by spatula. This method may be required for wounds having a narrow opening.

As stated above, the foam may also be produced on a suitable surface and then dried to produce the foam sheet described above. Generally, the production of the sheet will take place under sterile conditions or may be sterilised after production. In the prior described foam product of WO-A-96/17595, it was not possible to provide a foamed pad product and then sterilise the pad by conventional means such as γ-irradiation, since it was found that the foam structure deterioriated during sterilisation. With the inclusion of the precipitant however, sterilisation of the pad is possible both by γ-iradiation, ethylene oxide sterilisation or other conventional means. This represents a very considerable advantage over the prior art product. Optionally the manufacture of a prefoamed product may envisage a continuous foaming process. The sheet may be divided into a convenient size and may be packaged. Optionally the foam sheet may be produced on contoured surface so that it is moulded to a pre-determined shape.

Examples of suitable foamable carriers for use in the composition of the present invention include (but are not limited to) alginate and derivatives thereof, carboxymethylcellulose and derivatives thereof, collagen, polysaccharides (including, for example, dextran, dextran derivatives, pectin, starch, modified starches such as starches having additional carboxyl

and/or carboxamide groups and/or having hydrophillic side-chains, cellulose and derivatives thereof), agar and derivatives thereof (such as agar stabilised with polyacrylamide), carageenan, polyethylene oxides, glycol methacrylates, gelatin, gums such as xanthum, guar, karaya, gellan, arabic, tragacanth and locust bean gum. Also suitable are the salts of the aforementioned carriers, for example, sodium alginate. Mixtures of any of the aforementioned carriers may also be used, as required.

Preferred foamable carriers include alginate, carageenan, carboxymethylcellulose, the derivatives and salts thereof and mixtures of any of these. Alginate (the derivatives or salts thereof, such as sodium and calcium alginate) are especially preferred. Foamable carriers having a molecular weight of from 10,000 to 200,000 kDa are preferred, especially over 100,000 kDa, for example 150,000 to 200,000 kDa, may be used.

The formulation may further comprise a foaming agent, which promotes the formation of the foam. Any agent having a surfactant character may be used. The surfactants may be cationic, non-ionic or anionic. Examples of suitable foaming agents include cetrimide, lecithin, soaps, silicones and the like. Commercially available surfactants such as Tween™ are also suitable. Cetrimide (which additionally has an anti-bacterial activity) is especially preferred.

The formulation of the present invention (and thus the foam) may be used to deliver pharmaceutically active agents, in particular to deliver such agents in a controlled release manner. Mention may be made of:

Antiseptics, Antibacterials and Antifungal agents,

such as Chlorhexidine, acetic acid, polynoxylin, povidone iodine, mercurochrome phenoxyethanol, acridene, silver nitrate, dyes eg brilliant green, undecanoic acid, silver sulphadiazine, silver proteins and other silver compounds, metronidazole, benzaclonium chloride;

Nutritional agents, such as vitamins and proteins;

Growth factors and healing agents, including Ketanserin a serotonomic blocking agent;

Living Cells;

Enzymes include streptokinase and streptodormase;

Elements - zinc, selenium, cerium, copper, manganese, cobalt, boron, arsenic, chromium silver, gold, gallium;

Charcoal;

Desloughing and Debriding agents such as hypochlorite and hydrogen peroxide;

Astringents including potassium permanganate;

Antibiotics exemplified by neomycin and framycetin sulphate, sulfamylon, fusidic acid, mupirocin, bacitracin, gramicidin.

In addition the formulation of the present invention may further comprise other conventional additives such as plasticisers and humectants (such as glycerol, propan -1,2-diol, polypropylene glycol and other polyhydric alcohols), free radical scav ngers to

stabilise against the effects of sterilisation by irradiation, viscosity-adjusting agents, dyes and colorants, and the like.

Several experiments including comparatives tests have been achieved by the Applicant in order to demonstrate some of the advantages of the new compositions of the invention. Of course the embodiments described hereinbelow are submitted in order to better described the invention and not to limit its scope.

EXAMPLE 1

PROCEDURE FOR MANUFACTURE OF UNIT BATCH (100 g) of ALGINATE GEL

Typically the alginate gels are made according to the following process:

1. De-ionised (DI) water is measured and poured into mixing vessel 1.
2. Desired amounts of suitable alginate (for example Keltone) and glycerine are weighed using a calibrated balance, reading to 2 decimal places.
3. Alginate and glycerine are mixed together in a beaker until no lumps remain.
4. The whole alginate/glycerine mix is added very slowly to the water.
5. Once all the alginate/glycerine has been added to the water, the mixture is stirred until a smooth gel has formed.

Several different alginate gels have been made according the above process. They differ and are referred to by the amount of alginate (for example Keltone) used. For example the alginate gel code 6½ has

the following composition:

GEL CODE	6½
DI Water	80 ml
Glycerine	25.22 g
Keltone	6.5 g
Unit Batch Wt	111.72 g

The above composition can be varied to include other weights of alginate, which would be reflected in the gel code number. For example a composition having 8g alginate (plus 80ml DI water and 25.22g glycerine) would have gel code 8. Analogous gel codes are used when other gel formers (eg carageenan or CMC) are substituted for the alginate in the above composition.

PROCEDURE FOR FOAM PRODUCTION

The propellant used to produce the foam can be compressed gases such as air, nitrogen, nitrous oxide or air, hydrofluorocarbons such HFC134a or 227 or hydrocarbons including propane, isopropane, n-butane, isobutane and 2-methylbutane.

Propellant vapour pressure can range from 0 to 110 PSIG at 70°C although the preferred range is 20 to 70 PSIG. Values within this range can be achieved for example by blending the three hydrocarbons propane, isobutane and butane. Calor Aerosol Propellants (CAP) sold by Calor Gas Ltd Slough may be used as propellant gas, when a blend of propane, isobutane and butane is used the proportions can be as follows:

Grade	Propane %	Isobutane %	n Butane%
CAP 30	11	29	60
CAP 40	22	24	54
CAP 70	55	15	30

A foam according to the invention can advantageously be produced following the following process:

1. 100 g of a gel according to the invention is poured to an aerosol cannister.
2. 2.5 g of calcium citrate (food grade) is added to the cannister.
3. A valve is crimped onto the cannister.
4. Air is purged from the cannister.
5. 4.5 g of propellant gas is added into the cannister (65:35 CAP 40 : Isopentane propellant) and an actuator is positioned on the valve.
6. The cannister is shaken vigorously for 20-30 seconds.
7. the cannister is inverted and the foam dispensed.

EXAMPLE 2

Using a range of water-based gel formulations detailed below tests were done to improve the "setting" time and stability of the gel and its foam.

Preferred alginate compositions have an amount of Keltone ranging from 5-9g in the composition set out in Example 1.

Experiment 1. Gel Code 6½ Alginate gel and foam mixed with calcium citrate compared to Gel Code 6½ alginate gel alone

Foamed gel with calcium citrate

2.5 g calcium citrate was added to 100 g of gel and the

foamed gel was spread out onto plastic sheeting. The resultant foam pad was liftable in 15 minutes.

Foamed gel without calcium citrate

The above experiment was reproduced by foaming the gel on its own as described above. The "setting" time of the foam was 10 hours.

The experiments were repeated using 100 g unfoamed gel with and without calcium citrate. Similar setting times to those observed for the foamed gels were obtained (15 minutes and 10 hours respectively) before the gel pads were liftable.

Conclusion: Calcium citrate speeds up and controls the setting time of the gel and the foam.

Experiment 2. Gel Code 8 Alginate gel mixed with water soluble glass (WSG) containing phosphate and boron compared to gel code 8 alginate gel alone.

The WSG was comprised as follows:

28.5M% CaO

3M% Ag

5M% B_2O_3

18.5M% MgO

45M% P_2O_5

Foamed gel with WSG

2.5 g of WSG was mixed with 100 g gel and the foamed mixture was spread out onto plastic sheeting. The resultant foam pad was liftable in 120 mins.

Foamed gel without WSG

The above experiment was repeated by foaming the gel on its own. The "setting" time of the foam was

approximately 10 hours.

The experiments were repeated using 100 g unfoamed gel with and without WSG. Similar setting times to those observed for the foamed gels were obtained (120 minutes and 10 hours respectively) before the gel pads were liftable.

Conclusion: WSG speeds up and controls the setting time of the gel and the foam.

Experiment 3. Gel Code 4 Carageenan gel mixed with calcium citrate compared to gel code 4 gel alone

Foamed gel with calcium citrate

3 g of calcium citrate was mixed with 100 g gel and the foamed mix was spread out onto plastic sheeting. The resultant foam pad was liftable in 120 mins.

Foamed gel without calcium citrate

The above experiment was repeated by foaming gel on its own as described above. The "setting" time of the foam was 10 hours.

The experiments were repeated using 100 g unfoamed gel with and without calcium citrate. Similar setting times to those observed for the foamed gels were obtained (120 minutes and 10 hours respectively) before the gel pads were liftable.

Experiment 4. Gel Code 4½ Carageenan gel and gel code 6½ alginate gel mixed with calcium citrate compared to gel code 4½ carageenan gel and gel code 6½ alginate gel alone

Foamed gel with calcium citrate

2.5 g of calcium citrate was mixed with (50 g alginate and 50 g carageenan) gel and the foamed mix was spread out onto plastic sheeting. The resultant foam pad was liftable in 15 mins.

Foamed gel without calcium citrate

The above experiment was repeated by foaming the mixed gel on its own. The "setting" time of the foam pad was 10 hours.

The experiments were repeated using 100 g unfoamed gel with and without calcium citrate. Similar setting times to these observed for the foamed gels were obtained (120 minutes and 10 hours respectively) before the gel pads were liftable.

Experiment 5. Gel Code 6½ Alginate gel mixed with calcium citrate and added bentone IPM gel

2.5 g calcium citrate was added to 100 g of gel with 1g bentone IPM gel, admixed in an aerosol cannister and dispensed therefrom as a foam onto a plastic surface. The resultant foam pad was liftable in 12 minutes. Bentone IPM gel is an admixture of isopropyl myristate, sterealkonium hectorite and propylene carbonate.

Conclusion: Calcium citrate and bentone gel control the setting time of the foam. Bentone gel also acts as a reological agent and assists in the smoothness of delivery from the can.

Experiment 6. Gel Code 6½ Alginate gel mixed with calcium citrate and added cetrimide

2.5 g calcium citrate was added to 100 g of alginate gel with 1g cetrimide in an aerosol cannister and foamed onto a plastic surface. The resultant foam pad was liftable in 15 minutes.

Conclusion: Calcium citrate speeds up the setting time of the foam. Cetrimide increases the cell structure of the product.

Experiment 7. Gel Code 6½ Alginate gel mixed with calcium citrate and added Tween 20

2.5 g Calcium citrate was added to 100 g of alginate gel with 1g Tween 20 and foamed onto a plastic surface. The resultant foam pad was liftable in 12 minutes.

Conclusion: Calcium citrate speeds up the setting time of the gel. The additive Tween 20 gave a much smoother delivery and an airier foam. Tween 80, 60 and 40 were also tried and all assisted in the delivery and product cell structure.

Experiment 8. Gel Code 4 Carboxmethyl cellulose and gel code 6½ alginate gel mixed with calcium citrate compared to the gel alone

2.5 g calcium citrate was added to (50 g CMC & 50 g alginate gel) and then the mixture was foamed onto a plastic surface. The resultant foam pad was liftable in 25 minutes. The gel foamed on its own was liftable overnight (approx. 10 hours).

Experiment 9. Gel Code 4 Carboxmethyl cellulose gel mixed with aluminium chloride compared with the gel alone

2 g aluminium chloride was mixed with 100 g CMC gel. The gel was spread onto a plastic surface. The resultant gel was liftable instantly. The gel alone was liftable overnight (approx. 10 hours).

Experiment 10. Gel Code 6 Alginate gel mixed with citric acid compared to gel code 6 alginate gel alone

2.5 g of citric acid was mixed with 100 g alginate gel and the mix was spread out onto plastic sheeting. The resultant gel pad was liftable in 120 mins. 100 g of the gel alone was spread onto plastic sheeting and the resultant pad was only liftable overnight (approx. 10 hours).

Experiment 11. Gel Code 6½ Alginate gel was mixed with the following powders on a 100 g gel: 2.5 g powder basis

Powder	Results as a gel	Results as a foam
Calcium Chloride	Gel pad was formed instantly	Fast setting foam
Calcium Sulphate	Gel pad formed reasonably quickly	Foam set reasonably quickly
Aluminium Chloride	Gel pad formed instantly	Fast setting foam
Calcium Metaborate	Gel pad formed instantly	Fast setting foam

Experiment 12. Setting performances of a foam of a gel code 6½ alginate gel as a function of the amounts of calcium citrate.

Batch No	Amount of calcium citrate per 100 g gel	Result
DM02 210798	4 g	Not dispensed - set in can
DM03 210798	3 g	Very difficult to dispense. 9½ minutes to set.
DM04 210798	2.5 g	Easier to dispense than above. 18½ minutes to set
DM05 210798	2.25 g	Taking longer to set. 20 minutes.
DM02 200798	2 g	Setting time - 40 minutes

Experiment 13. Gel Code 6½ alginate gel with calcium vibrate and isopertrane.

100g gel code 6½ alginate gel was admixed with varying amounts of calcium citrate (2 to 4g), added to isopentane and mixed thoroughly before being spread onto a glass sheet. The isopentane vaporises at ambient temperatures and boils off through the gel leaving a foam pad of similar consistency to those produced by dispersion from an aerosol can. After half-an-hour the foam pads were liftable.

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Murgitroya & Co.

7/10/99